

Notice of Allowability

Application No.

10/626,894

Examiner

Raymond J. Henley III

Applicant(s)

SHALABY, SHALABY W.

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the papers as originally filed and the reply filed February 14, 2007.
2. ☒ The allowed claim(s) is/are 1-19.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 11/3/2003
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
- *7. ☒ Examiner's Amendment/Comment
- *8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

* Single document

RAYMOND HENLEY III
PRIMARY EXAMINER

AK 11/6/4

Examiner's Comments

Applicant's Information Disclosure Statement filed November 3, 2003 and Response to Election of Species Requirement filed February 14, 2007 have been received and entered into the application.

As reflected by the attached, completed copy of form PTO/SB/08B, (1 sheet), the cited references have been considered by the Examiner.

Applicant's election of the species of present claim 4, i.e., where the polyelectrolytes comprise an ionic conjugate of a polymeric phosphate glass or ceramic and a chitosan, without traverse, is noted. The Examiner has conducted a search in the relevant data bases and has found no art that would anticipate or render obvious the presently claimed subject matter where the polyelectrolyte is the elected species. Accordingly, the search has been extended and has encompassed the totality of subject matter presently claimed. As explained below, no art has been found which would anticipate or render obvious the full scope of the presently claimed subject matter. Accordingly, the election of species requirement, as set forth in the previous Office action dated January 16, 2007, is hereby vacated.

Reasons for Allowance

The present invention is directed broadly to, as set forth in present claim 1, an absorbable, conformable preform for use in making a solid bone filler which comprises an absorbable mixture of oppositely charged, solid microparticulate polyelectrolytes encased in a sealed, flexible, absorbable copolyester fabric construct and capable of undergoing solidification to a

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solid, integral mass having a modulus of more than about 0.5 GPa upon contact with an aqueous medium.

The reference discovered by the Examiner which is deemed most relevant to the claimed subject matter is Hammer et al., (U.S. Patent No. 6,989,034). Hammer et al. are directed broadly to a musculoskeletal tissue scaffold implant device which includes a tissue scaffold component fixedly attached to a scaffold fixation component via, *inter alia*, a fabric, (see the abstract). As shown in Figure 3, the patentees disclose a fabric (54) encased scaffold component (20) and scaffold support (32) where the fabric is attached to the a fixation post (34) of the fixation component (30) by an attachment means, (56), (see col. 2, lines 52-55 and col. 3, line 65 – col. 4, line 4). The scaffold component (20) may be a solid comprised of an absorbable ceramics or glasses, such as an electrolyte of which “calcium phosphates” are disclosed, (col. 5, lines 4-5).

In relation to the presently claimed subject matter, it is first noted that the present claims fail to exclude the fixation component, (30), of the patentees. The scaffold component (20) of the patentees would meet the requirements for an absorbable composite preform for use in making a solid bone filler which is comprised of a mixture of oppositely charged, solid polyelectrolytes. In particular, the plurality of calcium phosphate particles would serve both the anionic and cationic, i.e., negative charged and positive charged, requirement of the claims as well as the requirement for a mixture of such electrolytes, (i.e., different electrolytes are not required). The scaffold component (20) is further seen to be encased by a fabric, i.e., the claimed “fabric construct”, and the fabric is “sealed”, even though to not a full extent, at the position (56) as seen in Fig. 3. From Fig. 3, while not expressly disclosed, it can be appreciated that the fabric is “flexible”.

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The implant device of Hammer et al., however, fails to have the following, required elements of the presently claimed composite preform. The Hammer et al. device, as a whole, is not seen to be “conformable” because both the fixation component (30) and scaffold component (20) appear rigid. The presently claimed preform is required to have a “solid microparticulate polyelectrolyte” element. Hammer et al. do not disclose or suggest a microparticulate form for their scaffold component (20). The presently claimed preform is required to have the polyelectrolytes encased in a sealed, flexible, absorbable copolyester fabric construct. Hammer et al. fail to disclose the composition of the fabric, (54), and thus fail to disclose that it may be polyester. Also, it may be interpreted that any one or all of (i) the presently claimed preform, as a whole, (ii) the polyelectrolyte portion, and/or (iii) the copolyester fabric construct is/are capable of undergoing solidification to a solid, integral mass having a modulus of more than about 0.5 GPa upon contact with an aqueous medium. Nothing disclosed by Hammer et al., or generally known in the art, leads the Examiner to conclude that such a property is existent in the device of Hammer et al. or would have been obvious.

When taken together, the teachings of Hammer et al. simply fail to teach or suggest the required elements of the presently claimed composite preform. Further, the Examiner is unaware of any teaching in the art that would have made obvious each and every one of the differences noted above so as to have lead one of ordinary skill in the art to the conclusion that the presently claimed composite preform would have been obvious.

Accordingly, the subject matter defined in Applicant’s claims 1-19 is deemed allowable.

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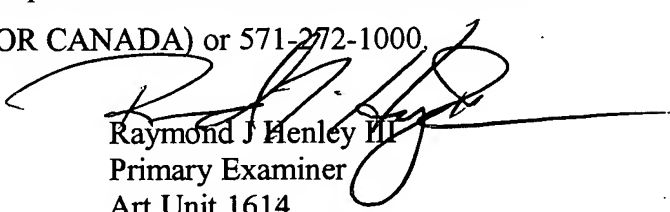
The remaining references cited by the Examiner are considered to show no more than the general state of the art. None of these references teach or would have made obvious the presently claimed subject matter.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Raymond J Henley III
Primary Examiner
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May 7, 2007